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(71) Applicant: ALZA CORPORATION [US/US]; 1900 Charleston Road, P.O. Box 7210, Mountain View, CA 94039-7210 (US).

(72) Inventors: CHEN, Guohua; 399 Sunset Avenue, Sunnyvale, CA 94086 (US). HOUSTON, Paul, Ricky; 3889 Blackstone Court, Hayward, CA 94542 (US). KLEINER, Lothar, Walther; 295 Los Altos Court, Los Altos, CA 94022 (US). WRIGHT, Jeremy, Corwin; 631 Cuesta Drive, Los Altos, CA 94024-4135 (US).

(74) Agents: DATE, Vandana et al.; ALZA CORPORATION, 1900 Charleston Road, P.O. Box 7210, Mountain View, CA 94039-7210 (US).

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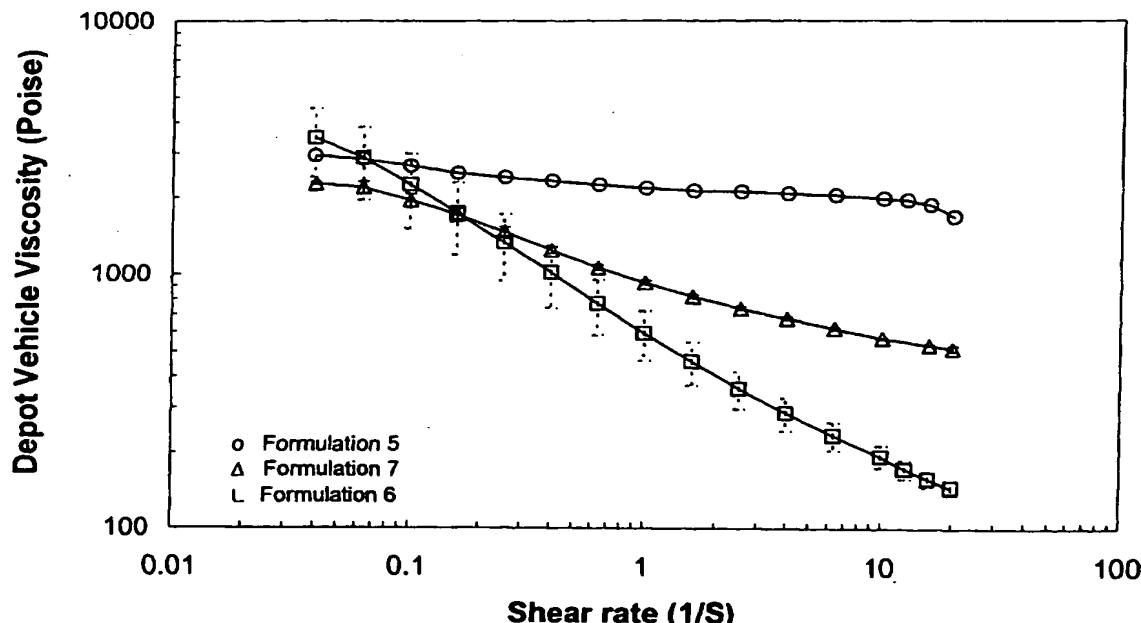
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(54) Title: INJECTABLE DEPOT COMPOSITIONS AND USES THEREOF



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(57) Abstract: Injectable depot compositions are provided that include a bioerodible, biocompatible polymer, an aromatic alcohol having miscibility in water of less than or equal to 7 wt.% at 25°C, in an amount effective to plasticize the polymer and form a gel therewith, and a beneficial agent. The composition may additionally contain an ester of an aromatic acid, or an aromatic ketone. The compositions are readily implanted beneath a patient's body surface by injection, as the aromatic alcohol not only facilitates solubilization of the polymer, but also acts as a thixotropic agent, substantially increasing the shear thinning behavior of the composition.

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/36715

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 24150 A (ZENECA LTD) 9 December 1993 (1993-12-09) page 26, paragraph 2 -page 29, paragraph 1 examples 16-20 claims ---	1-87
X	WO 95 13799 A (MEDISORB TECHNOLOGIES INTERNAT) 26 May 1995 (1995-05-26) example 1 ---	1-8
X	WO 98 27963 A (ALZA CORP) 2 July 1998 (1998-07-02) example 2 & US 613 200 A cited in the application ---	1-87

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *8* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

23 June 2003

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Epskamp, S

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 74650 A (ALZA CORP) 14 December 2000 (2000-12-14) example 1 ----	1-87
P, X	WO 02 067991 A (GENENTECH INC) 6 September 2002 (2002-09-06) examples claims -----	1-87

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INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 45-87 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/36715

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
WO 9324150	A 09-12-1993		AT 407702 B AT 901993 A AU 682310 B2 AU 4084793 A BE 1006143 A3 CA 2136751 A1 CH 688911 A5 CH 690491 A5 CZ 9402937 A3 DE 4392401 T0 DK 135394 A ES 2107357 A1 FI 945553 A FR 2691631 A1 WO 9324150 A1 GB 2282066 A ,B GR 1001550 B HK 133097 A HU 70177 A2 IE 930358 A1 IL 105710 A IT MI931099 A1 JP 8501064 T LU 88559 A1 MC 2330 A NL 9320034 T NO 944535 A NZ 252268 A RU 2152225 C1 SE 501970 C2 SE 9404115 A SG 44645 A1 SK 143494 A3 US 6034175 A US 5889110 A US 2002198315 A1 ZA 9303358 A	25-05-2001 15-10-2000 02-10-1997 30-12-1993 24-05-1994 09-12-1993 29-05-1998 29-09-2000 15-03-1995 24-07-1997 28-11-1994 16-11-1997 25-01-1995 03-12-1993 09-12-1993 29-03-1995 29-04-1994 24-10-1997 28-09-1995 01-12-1993 19-03-2001 28-12-1993 06-02-1996 05-04-1995 31-05-1994 03-04-1995 25-01-1995 20-12-1996 10-07-2000 03-07-1995 28-11-1994 19-12-1997 11-07-1995 07-03-2000 30-03-1999 26-12-2002 15-09-1994
WO 9513799	A 26-05-1995		AT 212830 T AU 684324 B2 AU 1101095 A AU 697887 B2 AU 3683197 A CA 2176716 A1 DE 69429820 D1 DE 69429820 T2 DK 729353 T3 EP 0729353 A1 EP 0998917 A1 ES 2172574 T3 JP 9505308 T PT 729353 T WO 9513799 A1 US 5654008 A US 5650173 A	15-02-2002 11-12-1997 06-06-1995 22-10-1998 20-11-1997 26-05-1995 21-03-2002 14-11-2002 27-05-2002 04-09-1996 10-05-2000 01-10-2002 27-05-1997 31-07-2002 26-05-1995 05-08-1997 22-07-1997
WO 9827963	A 02-07-1998		AT 203157 T AU 5609798 A	15-08-2001 17-07-1998

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/US 02/36715

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9827963	A	AU	739469 B2	11-10-2001
		AU	5615498 A	17-07-1998
		DE	69705746 D1	23-08-2001
		DE	69705746 T2	31-10-2001
		DK	949905 T3	22-10-2001
		EP	0949905 A2	20-10-1999
		EP	0959873 A2	01-12-1999
		ES	2158611 T3	01-09-2001
		GR	3036599 T3	31-12-2001
		HK	1020009 A1	02-11-2001
		JP	2002512597 T	23-04-2002
		JP	2001509146 T	10-07-2001
		NZ	335851 A	23-02-2001
		PT	949905 T	28-12-2001
		WO	9827962 A2	02-07-1998
		WO	9827963 A2	02-07-1998
		US	2003044467 A1	06-03-2003
		US	6468961 B1	22-10-2002
		US	2002034532 A1	21-03-2002
		US	6331311 B1	18-12-2001
		US	6130200 A	10-10-2000
WO 0074650	A	14-12-2000	AU	5462900 A
			CA	2372994 A1
			CZ	20014338 A3
			EP	1183010 A2
			HU	0201626 A2
			JP	2003501375 T
			NO	20015888 A
			WO	0074650 A2
WO 02067991	A	06-09-2002	US	2002173552 A1
			WO	02067991 A1

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